DETAILED ACTION

Applicants' arguments, filed 09/28/2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 15 and 31-35 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kimura et al. in view of Postma et al. (both cited by Examiner on 1/31/2008).

Applicant has submitted a Declaration on 09/28/2010 to support the allegation of obtaining unexpected and superior effects when treating COPD models with TA-270 as compared to an existing medication for COPD, theophylline. Particularly, applicant has provided empirical data showing that TA-270 has stronger inhibitory effect on the infiltration of inflammatory cells than theophylline in the airway, showing a greater decrease in total inflammatory cell count, macrophage count, lymphocyte count and neutrophils count.

The examiner does not find the argument regarding or the empirical data showing TA-270 having a stronger inhibitory effect on the infiltration of inflammatory cells than theophylline in the airway. It is noted that TA-270 was already known to have

greater inhibitory effect on infiltration of inflammatory cells into BAL fluid as compared to theophylline. Aoki et al. (Aoki et al. Eur. J. Pharmacol. (2000); 409:325-330) show at page 328, Table I and page 329, 2nd column, that TA-270 has superior inhibitory effect on the infiltration of inflammatory cells into BAL fluid than Pranlukast, i.e., theophylline. For example, referring to Table I, when the total inflammatory cell count is compared for 20 mg/kg theophylline and 20 mg/kg TA-270, one readily notices that the count for TA-270 is lower than the count for theophylline/Pranlukast.

It is noted that the 09/28/2010 Declaration provides no empirical data showing the effect of either TA-270 or theophylline on the RV (or FEV1) of the lung. Accordingly, applicant's arguments regarding improved RV imparted by TA-270 are not found to be persuasive. Even if, *in arguendo,* applicant had provided objective data showing unexpected and superior effects when treating COPD models with TA-270 as compared to an existing medication for COPD, theophylline, the proffered evidence is clearly not commensurate in scope with the claims because the test agents were administered intratracheally – which is not orally and does not support the scope of parenteral administration in the claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. S./
Examiner, Art Unit 1612

/Patricia A Duffy/
Primary Examiner, Art Unit 1645